REMARKS

Claims 7-23 are active in the present application.

The rejection of Claims 7, 8, and 10-11 under 35 U.S.C. §102(b) over McQuillen et al is obviated by the present amendment.

The claimed *E. coli* strains claimed in Claims 7, 8, 10-11, and 23 are not the same as the McQuillen et al *E. coli* for the reasons of record, which are further explained hereinbelow.

The present invention provides, in part, an isolated *Escherichia coli,* which has an ability to produce and accumulate arginine in a medium when the bacterium is cultivated in the medium, and which is *modified to have an enhanced ability to utilize acetate*, whereby the ability to produce arginine is enhanced compared to the unmodified bacterium (see Claim 7).

McQuillen et al discloses E. coli strain B, which is a wild type strain (see page 81, "Methods", line 1). However, McQuillen et al do not disclose or suggest making a mutant *E. coli* strain or modify a wild-type *E. coli* so that it may utilize acetate as in Claim 7.

Applicants point out that a wild type *E. coli* are unable to utilize acetic acid or acetate as the sole carbon source or which has been modified to utilize acetate. Applicants direct the Examiner's attention to *E. coli* strain 237 noted in the specification on page 8, line 14-19, which was unable to utilize acetic acid or acetate as a sole carbon source on an agar medium to grow or form colonies within two days at 37°C (see page 9, lines 1-6). In contrast, a mutant strain, which was modified to have an ability to utilize acetate (e.g., strain 382), does have this ability. Therefore, the disclosure of McQuillen et al fails to anticipate the presently claimed invention.

Furthermore, the Examiner asserts: "The burden is on Applicant to show that the reference microorganism does not absolutely produce arginine in a medium containing acetic acid or acetate as the lone source. The instant specification only indicates that the strain on

page 8 grows poorly but there is absolutely no indication that no arginine was produced." (page 6, lines 5-9 of paper number 11). However, present claim 7 recites, in part: "whereby the ability to produce arginine is *enhanced compared* to the unmodified bacterium." Applicants have shown adequate data to support this additional distinction between the presently claimed invention and the disclosure of McQuillen et al.

Moreover, the growth medium used to culture the *E. coli* strain in McQuillen et al contained significant amounts of glucose as the carbon source (see page 82, line 1), which is different from those bacteria claimed in, for example, Claims 8 and 9, which recite that the *E. coli* can grow on an agar medium using acetic acid or acetate as a sole carbon source.

The Examiner's attention is drawn to Table 2 on page 11 and Table 3 on page 12, which are reproduced below for the Examiner's convenience:

Table 2

Strain	Arginine (g/L)
237 (parent)	5.1
382 (acetate utilizing mutant)	12.0
383 (acetate utilizing mutant)	7.7

Table 3

Strain	Arginine (g/L)	Yield from glucose (%)
237 (parent)	4.5	5.2
382 (acetate utilizing mutant)	19.3	23.9

The Amendment and Request for Reconsideration filed on December 23, 2002, stated: "As is clearly evident above, the wild type 237 strain was unable to utilize acetate as the sole carbon source in producing L-arginine compared to bacterial strains, which had been modified to utilize acetate as the sole carbon source (strain 382)." In the Advisory Action, the

Examiner noted, "absolutely no acetic acid or acetate is present in the fermentation reaction (paper number 14, page 2, line 17-18). Inspection of the media conditions of Examples 3 and 4 confirm that this observation by the Examiner is correct. However, this observation by the Examiner is of minimal consequence, as the Examiner appears to have missed the clear difference in production of L-arginine in the strains of the present invention (i.e., strain 382) and the strain corresponding to McQuillen et al (i.e., strain 237). This clear difference, on its own, is sufficient to demonstrate that McQuillen et al cannot anticipate the claimed invention.

Moreover, Applicants draw the Examiner's attention to Table 1 (page 10), which corresponds to the experiment set forth in Example 2 and was performed in an acetate environment. For the Examiner's convenience, Table 1 is reproduced below:

Table 1

Strain	Growth (OD540) in liquid minimal medium For 16 hours with:	
	Glucose (0.5%)	Ammonia acetate (0.5%)
237 (parent)	1.8	0.4
382	1.5	1.0
383	1.6	0.7

As is clearly evident above, the wild type 237 strain was unable to utilize acetate as the sole carbon source in producing L-arginine to nearly the same efficiency compared to bacterial strains, which had been modified to utilize acetate as the sole carbon source (strain 382). Again, based on this showing it is clear that the present invention is distinct from that of McQuillen et al, and therefore this reference cannot anticipate the claimed invention.

In the Advisory Action, the Examiner attempts to support maintaining the anticipation rejection over McQuillen et al by questioning the adequacy of the data (see paper number 14, page 2, lines 14-16). In particular, the Examiner has focused on the differences in arginine production by strain 237 in Tables 2 and 3. However, Applicants submit that even one of high school level skill in the art would appreciate that the differences in the overall yield of strain 237 in Tables 2 and 3 is intimately correlated with differences in the growth conditions between Example 3 (see page 10) and Example 4 (see page 11), which underlie these data. Accordingly, this observation by the Examiner is of no moment.

Based on the foregoing, it is clear that the *E. coli* of McQuillen et al is not the same as those *E. coli* claimed, and therefore the present claims are not anticipated by the disclosure of McQuillen et al.

Applicants request withdrawal of this ground of rejection.

The rejection of Claims 7-8 and 10-11 under 35 U.S.C. §112, first paragraph, is traversed.

As stated in the Amendment and Request for Reconsideration, filed on July 18, 2002:

> As this rejection may apply to the present claims, Applicants note that deposit receipts for the deposited strains FERM BP-7925 and FERM BP-7926 were filed on June 22, 2001. These strains are specifically identified on page 8, lines 14-19 and page 9, lines 11-16. As noted on those pages, those strands have been deposited under the terms of the Budapest Treaty. In accordance with such deposit, Applicants submit that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

At page 4, lines 5-15 of paper number 11, the Examiner has required the addition of the identifying information set forth in 37 C.F.R. §1.809(d) to the specification. 37 C.F.R. §1.809(d) requires inclusion of the following information:

(1) The accession number for the deposit;

(2) The date of the deposit;
(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
(4) The name and address of the depository.

Applicants submit that no further amendment is necessary, since this information is already in the specification.

Specifically, Applicants point to page 5, 11-18, which provides the depository, date of deposit, and the accession number. In addition, Applicants point to Example 1 (page 8, line 4 to page 9, line 16), which fully describes characteristics of the deposited *E. coli* cell strains. In particular, these strains have an ability to produce and accumulate arginine in a medium when the bacterium is cultivated in the medium, and which is modified to have an enhanced ability to utilize acetate, whereby the ability to produce arginine is enhanced compared to the unmodified bacterium. Moreover, this information has been added to Claim 7. Therefore, Applicants submit that the present claims are drawn to a deposited material, as such the Examiner would be able to compare the presently claimed invention to any prior art. In fact, the Examiner has already compared the present invention to the prior art (i.e., McQuillen et al).

In the Advisory Action the Examiner has taken the position that "One of the basic issues which has not been addressed and supplied by Applicant is the requirement as noted by number (3) of page 5 of the remarks: "A description of the deposited biological material sufficient to specifically identify it and to permit examination" (paper number 14, page 2, line 18 to page 3, line 5). Specifically, the Examiner has taken the position that the specification must provide: (a) the morphological characteristics of the claimed cell strain in various growth mediums and comparisons to the parent strain with respect to shape and size dimensions; (b) the mode of proliferation; and (c) physiological characteristics pertaining to

fermentation and assimilation and a comparison to the parent strain (paper number 14, page 3, line 10-17). However, Applicants note that the U.S. Courts have long held that availability of a biological product via a public depository provides an acceptable means of meeting the written description and the enablement requirements of 35 U.S.C. §112, first paragraph (see *In re Argoudelis*, 434 F.2d 1390, 1392, 168 USPQ 99, 102 (CCPA 1970), enclosed herewith). Accordingly, Applicants submit that this ground of rejection by the Examiner is not tenable and must be withdrawn.

Withdrawal of this rejection is requested.

With respect to the non-elected claims drawn to methods of producing arginine (Group III, see Claims 15-22), Applicants request that upon finding that the elected group is found to be allowable (Claims 7-14), the corresponding non-elected process claims should be rejoined in accordance with MPEP §821.04.

Applicants submit that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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IN THE CLAIMS

Please amend the claims as follows:

7. (Amended) An isolated *Escherichia coli,* which has an ability to produce and accumulate arginine in a medium when the bacterium is cultivated in the medium, and which is modified to have an enhanced ability to utilize acetate, whereby the ability to produce arginine is enhanced compared to the unmodified bacterium.

8. (Amended) [An] The isolated *Escherichia coli* [which] according to claim 7, wherein the bacterium has an ability to produce and accumulate arginine in a medium when the bacterium is cultivated in the medium, and which forms a colony within 2 days at 37°C when the bacterium is cultivated on an agar medium containing acetic acid or acetate as a sole carbon source.

--23. (New)--

In re Argoudelis, De Boer, Eble, and Herr

(CCPA)
168 USPQ 99

Decided Dec. 17, 1970
No. 8347
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Specification - Sufficiency of disclosure (§ 62.7)

35 U.S.C. 112 does not require that microorganism, deposited by applicants with public depository, be available to general public at time of filing application; paragraph 1 of section 112 provides only that specification enable any person skilled in the art to make and use the invention; reliance on section 111 as establishing a general requirement that specification be enabling as of filing date is not well founded since that section merely refers to section 112 for requirements concerning the specification.

2. Specification - Sufficiency of disclosure (§ 62.7)

Faced with problem that they could not give a sufficient description of how microorganism, used as starting material, could be obtained from nature, and in response to requirements of 35 U.S.C. 112 for an enabling disclosure, applicants deposited cultures of microorganism in public depository in United States; this was done before United States patent application was filed; written description as originally filed included name of depository and its designation of the deposit, in addition to a complete taxonomic description of microorganism and detailed disclosure of process of producing antibiotic from microorganism; cultures are to be made available to public upon issuance of patent which refers to such deposit and prior to issuance of patent under conditions specified in Rule 14; this procedure meets requirements of section 112; any person skilled in the art with access to pending application under Rule 14 and 35 U.S.C. 122

can reproduce the invention from the written disclosure as it was originally filed; it is not necessary that general public have access to culture prior to issuance of patent; disclosure is sufficient to permit a thorough examination by Patent Office and to preclude possibility that patent could issue without any person skilled in the art being thenceforth enabled to make and use the invention.

3. Specification - Sufficiency of disclosure (§ 62.7)

Concern as to permanent availability of microorganism cultures deposited by applicants with depository is answered by facts that (1) public depository was used, (2) depository is operated by Government, (3) depository is under contractual obligation to place culture in permanent collection, to supply samples to persons entitled under Rule 14 and 35 U.S.C. 122 to access to application, and to supply samples to anyone seeking them once the patent issues, and (4) there is nothing to suggest that cultures will undergo any physical changes which will render them unusable; possibility that disclosure may some day become nonenabling is too speculative to render disclosure insufficient under 35 U.S.C. 112.

Particular patents-Composition of Matter

Argoudelis, De Boer, Eble, and Herr, Composition of Matter and Process, claims 1 to 8 and 10 to 15 of application allowed.

Case History and Disposition:

Appeal from Board of Appeals of the Patent Office; 157 USPQ 437 .

Application for patent of Alexander D. Argoudelis, Clarence De Boer, Thomas E. Eble, and RossR. Herr, Serial No. 147,873, filed Oct. 26, 1961; Patent Office Group 120. From decision rejecting claims 1 to 8 and 10 to 15, applicants appeal. Reversed; Baldwin, Judge, concurring with opinion.

Attorneys:

Roman Saliwanchik (Eugene O. Retter and George T. Johannesen of counsel) for appellant.

S. Wm. Cochran (R. E. Martin of counsel) for Commissioner of Patents.

Joseph Hirschmann, Wappingers Falls, N.Y., amicus curiae.

Judge:

Before Rich, Almond, Baldwin, and Lane, Associate Judges, and McManus, Judge, Northern District of Iowa, sitting by designation.

Opinion Text

Opinion By:

Almond, Judge.

This is an appeal from the decision of the Patent Office Board of Appeals affirming the rejection of claims 1-8 and 10-15 of appellants' application entitled "Composition of Matter and Process." [1] No claims have been allowed.

The claimed inventions are two new antibiotic compounds, sparsogenin and sparsogenin A, and a microbiological process for preparing them. Sparsogenin is produced by the microorganism Streptomyces sparsogenes var. sparsogenes. During the fermentation for sparsogenin, sparsogenin A is concomitantly produced. Sparsogenin has a broad spectrum of antibacterial activities, moderate activity against several fungi, and it also inhibits the growth of KB human epidermoid carcinoma cells in tissue culture. Sparsogenin A inhibits the growth of Gram-positive and Gram-negative bacteria; it also inhibits the growth of KB cells in tissue culture and Walker adenocarcinoma W-256 in mice.

Approximately three months prior to the filing of appellants' application in the Patent Office, appellants deposited two agar slants of the microorganism in the permanent culture collection of the United States Department of Agriculture depository at Peoria, Illinois. The culture was added to the permanent collection of microorganisms maintained at the depository and was assigned the numerical designation NRRL 2940.

At the time appellants' application was filed, it was disclosed on page one of the specification that

> The actinomycete used according to this invention, for the production of sparsogenin, has been designated as Streptomyces sparsogenes var. sparsogenes. One of its strain characteristics is the production of sparsogenin. A subculture of this variety can be obtained from the permanent collection of the Northern Utilization and Research Division, Agricultural Research Service, U.S. Department of Agriculture, Peoria, Illinois, U.S.A. Its accession No. in this repository is NRRL 2940.

All parties concede that with the microorganism at hand the invention can be reproduced without experimentation by one

of ordinary skill in the art from the disclosure that followed in the specification. A detailed taxonomic description of the microorganism was also disclosed.

During the course of prosecution the examiner rejected claims 4-8 under 35 U.S.C. 102 (b) as anticipated by a Japanese publication. [2] Appellants argued that the reference lacked an enabling disclosure. The final rejection was appealed and at the hearing before the Board of Appeals the board requested copies of the correspondence relating to appellants' culture deposit. Appellants submitted the requested papers.

The cover letter that accompanied the culture deposit requested that the depository

> * * * withhold distribution of this organism in accordance with the United States Patent Office Rules of Practice, Rule 14, until such time as a United States patent is issued to us which identifies this culture by the NRRL number assigned to it. We will be glad to notify you when such a patent issues.

The return letter from the curator of the depository stated in part:

> Furthermore, insofar as is practicable in carrying out the business of the Department of Agriculture, we shall refrain from distributing this culture pending the issuance of the patent to your Company, with the exception however that access to this culture will be granted by us upon receipt of written authorization from your Company specifying the name and our number of the culture and identifying the party who is to receive it.

Citing the above-quoted correspondence, the board entered a new rejection in accordance with Rule 196 (b). The claims were rejected under 35 U.S.C. 112, paragraph 1. [3] The board reasoned that "the subculture presently cannot be obtained by anyone except nominees of appellants' assignee" on written authorization, and that the deposited specimens are not part of the application and "could not be made a part by language used by appellants' assignee in making the personal deposit." A request for reconsideration was denied.

Renewed prosecution before the examiner resulted in a final rejection of all of the claims as based upon a disclosure defective under 35 U.S.C. 112, and of claims 4-8 as anticipated by the Japanese publication under 35 U.S.C. 102 (b).

In the second appeal, an augmented five-man board reversed the prior art rejection but affirmed the rejection based upon a deficient disclosure under 35 U.S.C. 112.

The board took the position that appellants were attempting to comply with the requirements for an enabling disclosure under paragraph 1 of § 112 by depositing the microorganism in a public depository, thus making the microorganism known and available to the public. Noting, however, that if the microorganism is to be considered known to the public, it must be available

to the general public at the time of filing, the board stated, 157 USPQ 437, 443:

> Appellants do not in fact show or attempt to show that at the time of filing the application the microorganism used was known and available to the public; it is clear from the record that the deposit was secret or confidential and was not available to anyone without appellants' permission.

[1] We do not think that 35 U.S.C. 112 requires that the microorganism be available to the general public at the time of filing the application. Paragraph 1 of § 112 provides only that the specification enable any person skilled in the art to make and use the invention. The reliance of the board on 35 U.S.C. 111 [4] as establishing a general requirement that the specification be enabling as of the filing date is not well founded since that section merely refers to § 112 for the requirements concerning the specification.

Ordinarily no problem in this regard arises since the method of preparing almost all starting materials can be set forth in writing if the materials are not already known and available to the workers in the art, and when this is done the specification is enabling to the public insofar as the public has access to the application under Rule 14 and 35 U.S.C. 122. Appellants, however, because of the particular area of technology involved,

cannot sufficiently disclose by written word how to obtain the microorganism starting material from nature.

It has been pointed out in the Amicus Curiae brief that the same predicament exists in the case of asexually reproduced plants. In regard to plants, a general dispensation from the requirements of § 112 has been accorded by 35 U.S.C. 162. It is urged that the same should be true here. We do not believe that a general dispensation from the statutory requirements of § 112 in the case of microorganisms is necessary, desirable, or within the province of this court to grant. Our task here is not to decide what the general rule should be or to create exceptions to the provisions of § 112, but rather to interpret and apply § 112 to the facts of the case before us. As far as we are able to determine, an issue like the one facing us has never been decided by the courts in this country; therefore, as a matter of first impression, it requires that we analyze anew all of the statutes, law, and circumstances pertaining to this issue.

[2] As mentioned, a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given. Such a description could only detail an experimental screening program similar to the screening programs followed in discovering the microorganism in the first instance. If the microorganism involved were of very common occurrence, it might be found in a relatively short time, but if it were not of common occurrence, it might not be found for a very long time, if found at all. The microorganism involved here, of course, was not known and available to the workers in the art since it was newly discovered by appellants.

Faced with this problem, and in response to the requirements of § 112 for an enabling disclosure, appellants deposited cultures of their microorganism in a public depository in the United States. This was done before the United States patent application was filed. The written description as originally filed included the name of the depository and its designation of the deposit, in addition to a complete taxonomic description of the microorganism and detailed disclosure of the process for producing the antibiotic from the microorganism. The cultures are to be made available to the public upon issuance of a United States patent which refers to such deposit and prior to issuance of said patent under the conditions specified in Rule 14. Appellants state that the practice of depositing cultures in a public depository has been used for over fifteen years. [5]

It is our opinion that this procedure meets the requirements of 35 U.S.C. 112. Any person skilled in the art with access to the pending application under Rule 14 and 35 U.S.C. 122 can reproduce the invention from the written disclosure as it was originally filed. Appellants assured this by the contractual provision which accompanied the culture deposit and which provided for distributing the deposited microorganism in accordance with Rule 14 until the patent issued. As Dr. Hesseltine, curator of the United States Department of Agriculture depository used by appellants, stated in an affidavit submitted to the Patent Office by appellants:

> Whenever a culture of a microorganism is sent to me * * * [by appellants' assignee] for deposit, I am informed by an accompanying cover letter if the culture is being deposited in connection with the filing of a patent application in the United States. * * * Also, the letter calls my attention to Rule 14 of the United States Patent Office Rules of Practice. I understand that Rule 14 provides that access will not be given to "any pending application or papers relating thereto, without the written authority of the applicant, or his assignee or attorney or agent, unless it shall be necessary to the proper conduct of business before the Office or as provided by these rules," i.e., the Rules of Practice in Patent Cases. In cooperating with a depositor, we refuse access to a culture to anyone not entitled to it under the provisions of Rule 14 and in requiring authorization from the applicant, or his assignee or attorney or agent, or the assurance of the Commissioner of Patents that access to the culture is necessary to the proper conduct of business before the Patent Office or is provided for by the Rules of Practice in Patent Cases.

It is not necessary that the general public have access to the culture prior to the issuance of the patent. The procedure used by appellants is sufficient to constitute a constructive reduction to practice and to entitle appellants to the benefits of a filing date since they clearly demonstrated that they had solved all technological problems involved in producing the invention. The disclosure is sufficient to permit a thorough examination by the Patent Office and to preclude the

possibility that a patent could issue without any person skilled in the art being thenceforth enabled to make and use the invention.

The fact that there can be no description in words alone of how to obtain the microorganism from nature does not mean that appellants must make the microorganism available to the general public at the time of filing the application. There is no good reason why an applicant who has invented a process and product involving the use of a new microorganism must surrender his starting materials to the general public before filing, whereas an applicant in the other arts need tell the public nothing until his patent issues. We do not believe that § 112 was designed to achieve such a result.

[3] The only rational ground for concern on the part of the Patent Office appears to be for the permanent availability of the deposited microorganism. The deposits are not a part of the patent application, and the Patent Office exercises no control over them. This concern may be justified in some situations. A similar problem was involved in In re Metcalfe, 56 CCPA 1191, 410 F.2d 1378, 161 USPQ 789, 792 (1969). In that case a starting material was described by reference to the trademark under which it was being sold. This court pointed out:

> * * * (1) there is always the possibility that sometime after the issuance of a patent, the disclosure which was initially enabling may become "unenabling" and (2) whether a given disclosure which identifies a material to be employed in the practice of the claimed invention is "enabling" within the meaning of 35 U.S.C. 112, must be decided by a rule of reason applied to the facts of the case.

After considering the facts, the court concluded that the possibility that at some future date one skilled in the art might no longer be enabled to practice the invention was too speculative to justify a holding that the disclosure was insufficient under 112.

Applying the same considerations in the present case, we note that (1) a public depository was used; (2) the depository is operated by a department of the United States Government; (3) the depository is under a contractual obligation to place the culture in the permanent collection, to supply samples to persons legally entitled under Rule 14 and 35 U.S.C. 122 to access to apellants' application, and to supply samples to anyone seeking them once the patent issues; and (4) there is nothing in the record to suggest that the cultures will undergo any physical changes which will render them unusable. We conclude that the possibility that the disclosure may someday become non-enabling is even more speculative than in Metcalfe, and hence does not render the disclosure insufficient under § 112.

The only issue on appeal is whether apellants' disclosure is sufficient under 35 U.S.C. 112, paragraph 1. For the reasons given above, we conclude that the disclosure is sufficient. Therefore, the decision of the board is *reversed.*

Footnotes

Footnote 1. Serial No. 147,873 filed October 26, 1961.

Footnote 2. The publication concerned an antibiotic named tubercidin, which appellants had disclosed as having properties similar to sparsogenin A.

Footnote 3. Paragraph 1 of § 112 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Footnote 4. Section 111 provides in part:

> Application for patent shall be made by the inventor, except as otherwise provided in this title, in writing to the Commissioner. Such application shall include: (1) a specification as prescribed by section 112 of this title * * *

Footnote 5. A brief general discussion of this practice can be found in Levy and Wendt, "Microbiology and a Standard Format for Infra-Red Absorption Spectra in Antibiotic Patent Applications," J.Pat.Off. Soc., Vol. 37, pp. 855-859, Dec. 1955.

Concurring Opinion Text

Concur By:

Baldwin, Judge, concurring.

I concur in the Court's decision and believe that the reasoning of the principal opinion is sound. Nevertheless, the importance of this decision impels me to set forth some of my own reasons for finding appellants' disclosure adequate under the first paragraph of 35 U.S.C. 112.

It is difficult to conceive that at this late date it has not been settled as to when (that is, at what time) a patent specification disclosure must comply with the requirements of the first paragraph of 35 U.S.C. 112. In any event, such apparently is the case. I submit that the uncertainty in this area, while at least partially due to the use of loose language and/or thinking in deciding earlier cases, may also be the result of a general unawareness of the fact that the "enablement" provisions found in 35 U.S.C. 112 (which, of course, antedate the present statute) actually play a dual role in our system of patent jurisprudence.

The first aspect of that role is to provide the assurance that the public will, in fact, receive something in return for the patent grant. This consideration is, of course, the full and complete disclosure of how to make and use the claimed invention. Thus, the patent adds a measure of worthwhile knowledge to the public storehouse. The incentive to give this added measure of knowledge to the public, which clearly promotes the progress of the "Useful Arts," is the primary justification for the existence of the patent system.

It should be apparent, however, that this first aspect of the enabling disclosure requirements of section 112, requires only that the adequacy of the teaching disclosure be measured as of the issue date [1] of the patent. There is no sense in making an applicant publicly disclose any part of his invention,

much less its very essence, before he has been assured that he will obtain the protection he is seeking in return for that disclosure.

Practical necessity, of course, requires that an application disclosure be intelligible and capable of evaluation *before* the issue date. The examining bodies of the Patent Office must be able to understand what a claimed invention is, how it works, what utility it might possess, before they can adequately determine whether such invention merits the grant of a patent. One of the considerations involved in that determination is whether the specification disclosure is such "as to enable any person skilled in the art to which [the invention] pertains, or with which it is most nearly connected, to make and use the same." Under my analysis, however, the reference point for this particular evaluation would be the potential issue date of the patent. No rejection on this basis [2] should be made unless the examiner is not satisfied that, *at the time a patent would issue,* its specification disclosure would be such that one of ordinary skill in the pertinent art reading that disclosure could understand the concept involved and would be able to make and use the invention claimed (aided only by his ordinary skill and such existent technology available to him as might be required by the disclosure).

Apart from considerations relating to the adequacy of the specification's teaching disclosure, however, the examination of every patent application involves the further questions of whether the applicant is entitled to a patent under the provisions of 35 U.S.C. 102 and 103. It is here where the enabling provisions of section 112 play their second role. Most, if not all, of the determinations involving the patentable merits of a claimed invention vis-a-vis the prior art require that the application filing date be regarded as the prima facie date of invention. This date is accorded not only to the particular claims which might be under consideration, but also to United States patents which might be asserted as references against those claims. Because the filing date is so important in determining patent rights, it is essential that there be no question that, *at the time an application for patent is filed,* the invention claimed therein is fully capable of being reduced to practice (i.e., that no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remain in order to obtain an operative, useful embodiment). Manifestly, the usual way in which an applicant provides such assurance that his invention has reached the necessary stage of completion is to include in the application a specification disclosure which, in itself, fully constitutes "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and [to] set forth the best mode contemplated * * * of carrying out [the] invention." Thus, when an application is examined for compliance with the enabling provisions of 35 U.S.C. 112, and the application filing date is used as the reference

point, the inquiry need not go beyond obtaining the assurance that the claimed invention has been fully completed (in the sense explained above).

In the present case there is no question that, *at the time the patent issues,* one of ordinary skill in this art will be able to make and use the claimed antibiotic compounds from the written description included in the specification coupled only with his ordinary skill and the critical microbes, which will then be readily available to him. Appellants have thus satisfied the first aspect of my analysis. Also, the procedure set up by appellants, including the contracted storage of the microbes with the public depository, when coupled with the written disclosure contained in the specification, satisfies me that anyone having ordinary skill in this art would recognize that the invention claimed was fully completed as of the filing date of the application. For these reasons, I find that appellants' specification fully complies with the requirements of the enabling provisions of the first paragraph of 35 U.S.C. 112.

Footnotes

Footnote 1. I am aware of broad statements in opinions to the effect that the teaching of the patent must be such as to "add to the sum of public knowledge" at the time the patent expires. Insofar as they might be interpreted as suggesting that a patent disclosure need not be enabling until the patent expires, such statements are incorrect and inapplicable to the issues here.

Footnote 2. Before too much concern is aroused at this point, it should be remembered that the "new matter" provision of 35 U.S.C. 132 would still be available to prevent issues such as that involved here from arising very often. In most cases, the proscription against new matter will keep an applicant from amending a specification which is not "enabling" at the filing date in order to make it such at any future date.

- End of Case -

